

**REMARKS**

Applicants respectfully request reconsideration and withdrawal of the outstanding objections and rejections, in light of the following remarks.

**Status of Claims**

Claims 1, 5 and 13 are pending for the Examiner's consideration.

For the reasons that follow, Applicants believe all Claims are now in condition for allowance.

**Rejection under 35 U.S.C. § 101**

Claims 1, 5 and 13 were rejected under 35 U.S.C. § 101 as allegedly being not supported by either a specific and substantial asserted utility or a well established utility.

For the reasons set forth in the July 10, 2007 Reply, Applicants maintain that Claims 1, 5 and 13 satisfy the utility requirement of 35 U.S.C. § 101.

Claim 1 is directed to an isolated human protein consisting of the amino acid sequence of SEQ ID NO:1. Claim 5 covers a medicament, comprising the protein according to claim 1. Claim 13 is directed to a kit for the detection of a human PTCH2 polypeptide comprising in a container a protein according to claim 1.

In compliance with the analysis outlined in the Revised Interim Utility Guidelines Training Materials, Applicants indicate that:

1. The specification discloses and provides the evidence that points to an activity of the claimed PTCH2 protein, for example, by showing a strong positive signal for PTCH2 mRNA exclusively in the tumor cells of all tested basal cell carcinomas (BCCs). See, for example, Paragraph [0082] of the originally-filed application. Therefore, there is a well established utility for the claimed invention.

2. Here, there is an asserted utility of the involvement of the claimed PTCH2 protein into the PTCH/SHH pathway, for example, during carcinogenesis, such as BCC. See, for example, Paragraph [0044] of the originally-filed application.

3. The utility is specific because there is a strong positive signal for PTCH2 mRNA exclusively in the tumor cells of all tested basal cell carcinomas (BCCs).

4. The specification teaches that the claimed PTCH2 protein is a candidate for a tumor suppressor gene in chromosome 1p32-35 and may be used in diagnostic methods. See, for example, Paragraph [0048] of the originally-filed application. Thus, the asserted utility is substantial.

5. The techniques related to gene/protein expression are well-known in the art. Accordingly, the use of the claimed PTCH2 protein, for example, in diagnostic methods is enabled, and the asserted specific and substantial utility is credible.

Applicants respectfully request that the rejection under 35 U.S.C. §101 be withdrawn.

**Rejection under 35 U.S.C. § 112, first paragraph**

Claims 1, 5 and 13 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly not teaching one of ordinary skill in the art to use the invention commensurate in scope with the claims. For the reasons set forth below, Applicants respectfully traverse this rejection.

According to the M.P.E.P. §2164.07 I.A, “Office personnel should not impose a 35 U.S.C. 112, first paragraph rejection grounded on a ‘lack of utility’ basis unless a 35 U.S.C. 101 rejection is proper.” Here, the Office fails to establish a proper utility rejection. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §112 be withdrawn.

**Rejection under 35 U.S.C. § 112, the first paragraph**

Claims 1, 5 and 13 were rejected under 35 U.S.C. § 112, the first paragraph, as allegedly being not enabling. Applicants maintain that the specification is enabling for the same reasons of record in the previous Response to the August 17, 2006 Office Action. The present invention is a pioneering work that provides a basis for further scientific developments as shown, for example, in the scientific publications on PTCH2 by the inventors and others included in the attached list.

Applicants respectfully request that the rejection under 35 U.S.C. §112 be withdrawn.

**Conclusion**

Applicants believe all claims are now in condition for allowance. Should there be any issues that have not been addressed to the Examiner’s satisfaction, Applicants invite the Examiner to contact the undersigned attorney.

Respectfully submitted,

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